Donald G. Norris (SBN 90000)
Douglas F. Galanter (SBN 93740)
Norris & Galanter LLP
523 W. Sixth St., Suite 716
Los Angeles, CA 90014
Tel: 213-232-0855
Fax: 213-286-9499
dnorris@norgallaw.com
dgalanter@norgallaw.com

William F. Cavanaugh (SBN 133461)
Scott B. Howard (admitted *pro hac vice*)
William F. Schmedlin (admitted *pro hac vice*)
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Telephone: (212) 336-2000
Fax: (212) 336-2222
wfcavanaugh@pbwt.com
sbhoward@pbwt.com
wschmedlin@pbwt.com

Attorneys for Defendants

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, VALEANT PHARMACEUTICALS INTERNATIONAL, INC., AND GALDERMA LABORATORIES, L.P.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE

FILED UNDER SEAL

Date: June 22, 2015
Time: 10:00 a.m.
Ctrm: 10D
Judge: Hon. Andrew J. Guilford

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

I. PRELIMINARY STATEMENT

Before the relevant patent claim language had been construed in this case, in filings with this Court Allergan had acknowledged that physicians had engaged in pre-mixing at the time of the alleged invention by using lidocaine with dermal fillers, including those comprised of HA-BDDE like Restylane (and, subsequently, Juvederm). This was consistent with testimony under oath by the inventor, contemporaneous articles, and documents produced by both Plaintiffs and Defendants. Yet, briefly before serving their opening expert reports on Galderma[1], Allergan reopened the issue by refusing to admit the same pre-mixing they had earlier conceded to this Court in their claim construction briefing. Moments later, Allergan served its own opening expert reports, including Dr. Lupo's discussion of her own pre-mixing activities. In her expert report, Dr. Lupo opined how, based on her prior use, pre-mixing lidocaine with a dermal filler was not acceptable to doctors. (Ex. A at ¶¶ 46-48).

Galderma addressed both the timing of pre-mixing and the efficacy and ease of pre-mixing in its rebuttal reports, properly challenging the opinions raised in the Allergan's first round of expert reports. This was relevant to show both that there was no long-felt need for the claimed invention and that doctors premixing lidocaine with a HA dermal filler would be an acceptable noninfringing alterative. There is no challenge that these issues were timely raised in the rebuttal reports.

When Allergan raised objections regarding the sufficiency of the allegations in the rebuttal report in their Motion for Partial Summary Judgment,

[1] For purposes of this motion, all references to Galderma refer collectively to all of the Defendants.

Galderma provided additional factual support promptly and during the fact and expert discovery period. Allergan, in this motion, reiterates arguments from their Motion for Partial Summary Judgment and attacks the additional corroboration pointed to by Galderma in response to that motion.

There is nothing untimely about Galderma's actions. As set forth in detail in Galmdera's opposition to the motion for partial summary judgment (D.I. 133), Galderma's invalidity expert report regarding physician's premixing and then selling combination injections of HA-BDDE dermal fillers and lidocaine was both timely and sufficient. Furthermore, the discovery schedule in this case set forth the times for Galderma submitting expert reports relating to the issues of secondary considerations and damages. Galderma's expert reports on those topics that discuss pre-mixing were similarly timely. There is no basis for Allergan's motion to strike evidence of premixing.

II. STATEMENT OF FACTS

A. Evidence of Prior Use

From early in the litigation, the parties acknowledged that dermatologists and other users of HA dermal fillers, such as Restylane and, later, Juvederm, pre-mixed these dermal fillers with lidocaine. Allergan explicitly told this Court as much in their June 22, 2014 Opening Claim Construction Brief:

> Dr. Pierre Lebreton began working on these compositions in the mid-2000s. ***At that time***, physicians were commonly treating patients with lidocaine either topically or by injection before injecting the HA filler.
>
> Alternatively, ***some physicians were mixing lidocaine into the HA filler immediately before injection.***

(D.I. 61 at 4 (emphasis added).)

Allergan, while acknowledging this prior use, argued that it did not practice the claims, contending that "the mixing was not precise and changed the properties (*e.g.*, viscosity) of the HA filler." (*Id.* at 4–5.) [redacted]

As discovery progressed, the supporting evidence for the pre-mixing of lidocaine and HA dermal fillers before the priority date of the patents only increased:

[redacted]

- Former Medicis employee Steve Newhard testified that he and Medicis were aware of pre-mixing from nearly the point when Restylane was first introduced (Ex. H at 200:13-18);

[redacted]

[2] [redacted]

Allergan's own experts offered testimony and report language supporting their original admission to the Court. Dr. Lupo testified at her deposition that at least two physicians told her that they began pre-mixing in 2007 (Ex. K at 14:7-9, 17:3-9) and that she began pre-mixing herself by late 2007 or early 2008 (*id.* at 198:11-17).

Relying on Allergan's admission to the Court regarding pre-mixing, such as that described in the *Beasley* article (Ex. L), Dr. Prestwich opined that some of the claims were invalid as anticipated or obvious over the pre-mixing prior art. (*See, e.g.*, Ex. M at ¶¶ 182-186.)

B. Allergan's Reversal

As a formality, to obtain a more succinct admission for use at trial, Galderma served its First Set of Requests for Admission ("RFAs") on Allergan in January of 2015. (Ex. N). These RFAs included items directed toward the pre-mixing of lidocaine with HA-BDDE dermal fillers. On February 17, 2015 – just shortly before serving their own opening expert reports – Allergan sought to distance itself from their earlier admissions to the court regarding pre-mixing. In response to Galderma's RFAs, Allergan claimed to have "no knowledge" of (a) any physician in the United States adding lidocaine to Restylane®, Perlane®, or Juvederm® products before August 4, 2007 (Ex. O at 3–4); or (b) any physician in the world adding lidocaine to Restylane®, Perlane®, or Juvederm® products before 2005. (*Id.* at 4–5.)

By that point, Galderma had already drafted its final invalidity contentions (Ex. P) and served them at the time of their opening expert reports in accordance with this Court's rules. Taking into consideration Allergan's prior acknowledgment that there was pre-mixing at the time of the alleged invention,

Galderma's expert Dr. Glenn Prestwich had completed drafting his report in which the routine pre-mixing was referenced and included an article describing the pre-mixing practice that had already become established as "routine" by 2009.

C. Galderma's Added Evidence of Pre-Mixing

While pre-mixing was relevant to the issues raised in Galdemra's opening round of expert reports, it was highly material its rebuttal reports on both secondary considerations of obviousness and damages. In light of Allergan's efforts to distance itself from a prior concession, Galderma supplemented the record with additional evidence of pre-mixing, consistent with that identified in its opening expert reports. For example, in his expert report, Dr. Nestor stated that "I and other doctors began pre-mixing lidocaine into Restylane® (a process Dr. Lupo describes as 'swishing') prior to 2006." (Ex. Q at ¶ 45.) Dr. Nestor referenced the Beasley article cited by Dr. Prestwich and an internet article from 2009 showing the continued, long-term practice of pre-mixing.

When Allergan made additional corroboration demands[3], Galderma responded by providing a declaration from Dr. Nestor's physician assistant, Julie Santos, and pointing to documents and testimony from both parties. (Ex. R.)

Allergan now seeks to "strike Defendants' invalidity contentions related to prior use in their entirety, or, at a minimum, limit them to only what is cited and discussed in the contentions" themselves. (D.I. 136-1 at 13).[4] Allergan also seeks to strike some, but not all, references to premixing in various depositions and reports.

[3] The question of whether additional corroboration was necessary is addressed in Galderma's Opposition to Plaintiffs' Motion for Partial Summary Judgment.

[4] Plaintiffs do not seek to strike the use of documents or Dr. Nestor's report or testimony as it relates to pre-mixing for purposes not related to the invalidity of the patent. Discussion of pre-mixing for damages and secondary considerations purposes would therefore remain permissible.

III. ARGUMENT

Galderma timely submitted both opening and rebuttal expert reports that discuss doctors pre-mixing HA dermal fillers – including HA-BDDE dermal fillers – with lidocaine prior to injecting the fillers into patients. Furthermore, because Allergan has had sufficient time to conduct full discovery and prepare expert reports on the issue of pre-mixing, it has not been prejudiced by the timing of Galderma's disclosures. Finally, even if the disclosure in Galderma's opening report was insufficient or untimely – which it is not – Galderma timely submitted expert reports discussing premixing with regard to secondary considerations and damages. As such, there is no basis for excluding the evidence from trial.

A. Galderma's Final Invalidity Contentions Contained the Requisite Amount of Information Given Allergan's Binding Admission to the Court

Allergan bound itself when it admitted to this Court that pre-mixing of lidocaine and HA-BDDE dermal fillers was occurring at the time of Dr. Lebreton's alleged invention. It was with this understanding that Galderma was operating throughout discovery, through submission of its Final Invalidity Contentions.

Galderma does not dispute that Section 2.5.1 of the Standing Patent Rules state that "[p]rior art under 35 U.S.C. Sec. 102(b)/(a) shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known." S.P.R. 2.5.1.

"The purpose of invalidity contentions is to require a party to crystallize its theories of the case early in the litigation and provide notice of the accusing party's

specific theories of invalidity." *See Wonderland Nurserygoods Co. v. Thorley Indus., LLC*, 2013 U.S. Dist. LEXIS 80003, at *7 (W.D. Pa. June 7, 2013) (internal quotation omitted); *see also O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365 (identifying the purpose of the invalidity contentions and discovery process as allowing "the plaintiff to pin down the defendant's theories of defense."). However, the purpose of the notice provision is muted when it is the plaintiff who provides the details of the prior art public use and sale.

In this case, Allergan admitted to this Court about doctors mixing lidocaine into HA-BDDE dermal fillers at the time that Dr. Lebreton – the inventor of the patents-in-suit – began working on the invention. In its June 2014 Opening Markman Brief, Allergan unequivocally stated:

> Dr. Pierre Lebreton began working on these compositions in the mid-2000s. ***At that time***, physicians were commonly treating patients with lidocaine either topically or by injection before injecting the HA filler. Alternatively, ***some physicians were mixing lidocaine into the HA filler immediately before injection.***

(D.I. 61 at 4 (emphasis added).) Unlike situations where a single prior use is alleged by a party, Allergan's own admission shows that this practice was widespread. Galderma served its First Set of RFAs not because the issue was unsettled. It is common to obtain via RFAs simpler admissions of already confirmed items for use at trial.

For example, Allergan did the same regarding infringement of its patents in light of this Court's claim construction. Even before ultimately determining that it would not contest *any* infringement claims, under the Court's claim construction, Galderma conceded nearly all elements of the patent claims asserted by Allergan [redacted]

Counsel for Galderma confirmed to counsel for Allergan on November 14, 2014 that

Galderma "was not contesting Allergan's infringement claims for those elements" that had blank boxes in Galderma's response. (Ex. T.) After Galderma confirmed that they were not contesting these claims as construed, Allergan served several sets of RFAs seeking admissions on those same items. On December 8, 2014, Allergan served one set of RFAs on various properties of Restylane-L and Perlane-L relevant to the patent claims, such as whether lidocaine was freely released in vivo and whether the extrusion force was substantially constant for at least 9 months. (Ex. U.) None of these were contested by Galderma. On January 8, 2015, Allergan served one set of RFAs confirming the degree of crosslinking in Restylane-L and Perlane-L was less than about 5%. (Ex. V.) This, too, was not contested by Galderma.

As discussed in Galderma's opposition to Allergan's motion for partial summary judgment (D.I. 133), Galderma fully complied with the notice requirements of the local rules regarding the use of pre-mixing. As such, there is no basis for excluding the evidence of pre-mixing.

B. Allergan Was Not Prejudiced and Will Not Be Prejudiced Due to the Pre-Mixing Disclosures

Additionally, Allergan would not suffer any undue or unfair prejudice by permitting the use of the full Final Invalidity Contentions and the cited documents, testimony, and report portions related to the prior use of pre-mixing. Perhaps realizing their responsibility for the confusion, caused the issue above Allergan attempts to manufacture a lack of good cause in support of its argument. They are incorrect.

As noted above, Allergan set forth its position regarding pre-mixing of lidocaine and HA-BDDE in their Opening Claim Construction brief. Allergan was also aware of Galderma's position on pre-mixing. Counsel for both Allergan and Galderma included questions on pre-mixing in their depositions of fact witnesses prior

to opening expert reports. For example, counsel for Allergan asked former Medicis employee Steve Newhard about his and Medicis's knowledge of pre-mixing by physicians, which he confirmed they were aware of shortly after their lidocaine-less products were on the market. (Ex. H at 200:13-18.)

Allergan's claims of prejudice revolve around their claim that they lacked an opportunity to respond in a rebuttal report and that they were unable to draft their summary judgment motion to refer to an earlier conception date instead of the priority date they utilized. However, neither demonstrates prejudice.

First, there is no need for Allergan to submit a further report on pre-mixing. Allergan has always known premixing was an issue and addressed it in their opening reports prior to Allergan seeing Drs. Prestwich's and Nestor's reports. For example, Dr. Lupo discussed pre-mixing – referred to as swishing – in her opening expert report. This included not only a discussion of what happened, but also some of its alleged shortcomings. (Ex. A at ¶¶ 46-48.) There is no prejudice to Allergan.

Second, Allergan's complaint about being unable to establish an earlier priority date is absurd. Early in the case, Galderma served an interrogatory on

Allergan asking for a date of invention and evidence of the same. (Ex. X.) [redacted] In response, Galderma identified 102(a) prior art [redacted] While Allergan chose not to use that evidence in its summary judgment motion to avoid raising a fact issue, that was a tactical choice by Allergan.

Additionally, because the premixing of lidocaine and HA-BDDE is 102(b) as a prior use and sale of the alleged invention, there would be no reason for Allergan to establish in its partial summary judgment motion an earlier invention date. Before the passage of the AIA, 102(b) posed as a bar to a patent the "public use or on sale in this country, ***more than one year prior to the date of application for patent in the United States.***" 35 U.S.C. 102(b) (emphasis added). Unlike a prior use under section 102(a), a patentee cannot use an earlier date of invention to swear behind 102(b) prior art. Because the pre-mixing is both 102(a) and 102(b) prior art, it is immaterial that Allergan did not establish an earlier date of invention.

Allergan's citation to *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.* is misplaced. Unlike the situation in *O2 Micro*, fact discovery had not – and still has not – ended. At the time that opening expert reports were exchanged, fact and expert discovery were scheduled to remain ongoing for nearly another three months. During this time, more support for Galderma's position on pre-mixing – a position that did

not become a factual issue until opening expert reports had been served – came to light. Documents Allergan requested from Q-Med were originally produced after the opening expert reports were served. The 30(b)(6) witnesses for Galderma and fact witnesses for Q-Med were deposed after the opening expert reports were served. Allergan's experts were deposed after the opening expert reports were served. To claim that it would be improper to utilize any of this discovery would run counter to the purpose of fact discovery.

After his expert report was submitted, Allergan deposed Dr. Nestor. This provided them ample opportunity to question him about his pre-mixing history and practices. Despite the fact that Galderma identified him both as an expert witness and a fact witness on the issue of premixing, Allergan chose not to ask him a single question on the topic. To the extent they wish to depose Julie Santos, they are welcome to do so. Discovery has not ended, and there is no reason why Allergan should not be able to utilize the available time.

For the above reasons, Allergan would experience minimal prejudice from the addition of the prior use of pre-mixing.

C. Pre-Mixing Is Relevant To Secondary Considerations And Damages

As discussed earlier, Galderma is relying on evidence of pre-mixing for various issues. Although Allergan's motion focused on one of those issues – as prior art that renders some of the claims invalid – it noticeably ignores the other issues that premixing is relevant towards.

For example, Galderma's damages expert, Dr. Bell, has opined, based on Dr. Nestor's report, that pre-mixing is an acceptable noninfringing alternative that defeats most of Allergan's claim for lost profit. Similarly, Dr. Bell also uses the alternative of premixing in determining the reasonable royalty rate in the event that

the claims are found valid. (Ex. AA at ¶¶ 35, 49, 70.) There have been no claims that Dr. Bell's report is in any way untimely or deficient.

Similarly, Dr. Prestwich relies on Dr. Nestor's opinion on premixing in his rebuttal secondary consideration report. Unlike his opening report on invalidity, there are no challenges to the timing or sufficiency of his report on secondary considerations. Thus, regardless of whether Galderma can argue that premixing either anticipates or renders the claims obvious, there are unobjected to uses of historical pre-mixing. Since there are unobjected to uses for evidence of pre-mixing, it is improper to strike such evidence entirely.

IV. Conclusion

For the foregoing reasons, Galderma respectfully requests the Court to deny Allergan's motion to strike.

Dated: June 1, 2015

/s/ William F. Cavanaugh, Jr.
William F. Cavanaugh, Jr.

PATTERSON BELKNAP WEBB & TYLER LLP
Attorneys for Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on June 1, 2015 to all counsel of record via electronic mail.

/s/ William F. Schmedlin
William F. Schmedlin